RESPONSE

I. Status of the Claims

Claim 1 has been amended. Claims 1-7 are presently pending.

II. Support for the Amended Specification and Claims

Amended Claim 1 has been amended for clarity at the Examiners request. New claim 1 finds support from original claim 1, previously presented claim 1 and SEQ ID NO:1 from the originally filed sequence listing.

III. Rejection of Claims 1-7 Under 35 U.S.C. § 101

The Action next rejects claims 1-7 under 35 U.S.C. § 101, because the claimed invention is not supported by either a specific and substantial asserted utility or well-established utility. Applicants respectfully traverse.

The Action discounts many of the numerous utilities described in the specification for the sequences of the present invention based on the position that while credible, these utilities are not specific or substantial. While Applicants in no way agree with the Examiner's arguments, Applicants have chosen to expand on only a few of the utilities as only one is required.

Applicants respectfully submit that the legal test for utility involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the

art, the Examiner should not impose a rejection based on lack of utility (66 Federal Register 1098, January 5, 2001).

In *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

> At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (C.C.P.A. 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable

amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Even under the newly installed utility guidelines, Applicants note that MPEP 2107 (II)(B)(1) states:

> (1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. (MPEP 2107 (II)(B)(1))

Applicants have asserted, and the Examiner appears to acknowledge that the sequences of the present invention encode a novel human semaphorin protein (for example, in the title of the application). The Action provides a summary of semaphorins as a group, but still the Examiner finds that the sequences of the present invention lacks patentable utility due to a lack of specificity. Applicants respectfully disagree and invite the Examiners attention to **Exhibit A** which is a sequence alignment between SEQ ID NO: 1 and GENBANK accession number NM_153618 (summary provided as **Exhibit B**). NM_153618 is annotated as a transcript variant (4) of human semaphorin 6D (SEMA6D). From the alignment provided one can see that the coding sequence provided in the SEQ ID NO:1 is 99.969% encoded within the transcript of NM_153618. Thus it is clear that the sequences of the claimed invention encode a variant of human semaphorin 6D.

Applicants further submit a scientific publication by X. Qu *et al.*., 2002 (JBC **227**:35574-35585: a copy is provided as **Exhibit C**). This publication is contemporaneous with the filing of the instant Application and thus provides evidence that those of skill in the art, in China, did recognize the

specific utility of the sequences of the present invention at the time the present application was filed. Also provided is a copy of an additional publication (T. Toyofuku *et al.*, Genes Dev **18**:435-447, 2004, **Exhibit D**) confirming and elaborating on the specific utility of Sema6D, the protein encoded by the sequences of the present invention. Thus clearly the claimed sequences have specific patentable utility.

The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given the clear recognition of those of skill in the art as described in the referred to publication, there can be no question that those skilled in the art would clearly believe that the molecule encoded by the sequences of the present invention have specific, substantial and well established and "real world" utility. As such, the scientific evidence provided clearly establishes that Applicants have described an invention whose utility is in full compliance with the provisions of 35 U.S.C. § 101, and therefore Applicants respectfully request withdrawal of the rejection.

The question of utility is a straightforward one. As set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made

by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility. Therefore , the present claims clearly meet the requirements of 35 U.S.C. § 101.

Although the above discussion is believed to be dispositive of the utility issue, Applicants would like to further direct the Examiner's attention to the parts of the specification that describe the use of sequences in a gene chip format to provide a high throughput analysis of the relevant cellular "transcriptome", including assessing temporal and tissue specific gene expression patterns, particularly using a high throughput "chip" format (specification at or about page 6, line 24 through page 9).

Evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, one such company, Rosetta Inpharmatics, was viewed to have such "real world" value that it was acquired by large pharmaceutical company, Merck & Co., for substantial

sums of money (net equity value of the transaction was $620 million). The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established. Clearly, persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, *e.g.*, Venter *et al.*, 2001, Science *291*:1304, presented as **Exhibit E**). The results have been a stunning success as the utility of human genomic data has been widely recognized as a great gift to humanity (see, *e.g.*, Jasny and Kennedy, 2001, Science *291*:1153, presented as **Exhibit F**). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years). The sequences of the present invention have particularly specific utility in DNA gene chip based analysis as they have been identified to contain several coding region single nucleotide polymorphisms (cSNPs), thus increasing their utility in DNA gene chip based analysis.

DNA chips clearly have utility, as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776 (**Exhibits G-L**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy). Accordingly, the present sequence has a specific utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, like the present sequences, which encodes a novel human semaphorin (Sema6D) proteins, that has been associated with may human porcesses, must have utility. The sequences of the present invention which encode a human semaphorin (Sema6D) protein and thus provides a specific marker for the human genome (see

also chromosome mapping discussion below and information provided in the specification at page 18, lines 6-7 that indicate that this protein is encoded on human chromosome 7). Thus, those skilled in the art would instantly recognize that the sequences of the present invention would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips, as the specification details. Accordingly, the present sequence has a specific utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequence encoding a novel human semaphorin (Sema6D) protein, must also be useful.

The Examiner is further requested to consider that, given the huge expense of the drug discovery process, even negative information obtained using these specific markers of expression of a human semaphorin (Sema6D) protein provides a very specific markers for the human genome and have great "real world" practical utility. Knowing that a given gene is not expressed in medically relevant tissue provides an informative finding of great value to industry by allowing for the more efficient deployment of expensive drug discovery resources. Such practical considerations are equally applicable to the scientific community in general, in that time and resources are not wasted chasing what are essentially scientific dead-ends (from the perspective of medical relevance). Clearly, compositions that enhance the utility of DNA gene chips, such as the presently claimed sequences encoding a human semaphorin (Sema6D) protein, must in themselves be useful. Moreover, the presently described human semaphorin (Sema6D) protein sequences provide uniquely specific sequence resources for identifying and quantifying full length transcripts that were encoded by the corresponding human genomic locus. Accordingly, there can be no question that the described sequences provide an exquisitely specific utility for analyzing gene expression. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Further evidence of utility of the presently claimed polynucleotide, although only one is needed to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), is the specific utility the present nucleotide sequence has in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions as described in the specification. Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome 8 containing the gene encoding this protein, a utility not shared by virtually any other nucleic acid sequence. In fact, it is this specificity that makes this particular sequence so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequence.

The Action discounts Applicant's assertion regarding the use of the presently claimed polynucleotides for gene mapping and determining chromosome structure again based on the position that such a use would allegedly be generic and therefore fail to represent a specific and substantial utility. However, as only a minor percentage of the genome actually encodes exons, which in turn encode amino acid sequences, the presently claimed polynucleotide sequence provides biologically validated empirical data (*e.g.*, showing which sequences are transcribed, spliced, and polyadenylated) that *specifically* defines that portion of the corresponding genomic locus that actually encodes exon sequence. Equally significant is that the claimed polynucleotide sequence defines how the encoded

exons are actually spliced together to produce an active transcript (*i.e.*, the described sequences are useful for functionally defining exon splice-junctions). The Applicants respectfully submit that the practical scientific value of expressed, spliced, and polyadenylated mRNA sequences is readily apparent to those skilled in the relevant biological and biochemical arts. For further evidence supporting the Applicants' position, the Board is requested to review, for example, section 3 of Venter *et al.* (*supra at* pp. 1317-1321, including Fig. 11 at pp.1324-1325), which demonstrates the significance of expressed sequence information in the structural analysis of genomic data. The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome essentially as described in the Venter *et al.* article.

In addition, among other things the mapping of the relatively few expressed human genes to a particular chromosome has long been a recognized method of identifying a genes associated with particular diseases. Furthermore, the mapping of the human chromosome is a project of such widely recognized importance by those of skill in the art and even lay people, that both the US government and private corporations have dedicated millions of dollars to such a project. One is thus forced to ask, if the mapping of human chromosomes is a throw away utility then why has the US government spent so many taxpayer dollars on this project? The Action's position is that this utility, like the use of these specific sequences on DNA chips or the described polymorphisms in forensic analysis, is that since other molecules can be used to map the human chromosome or on DNA chips or in forensic analysis, these utilities are not specific or substantial. As described previously above, Appellants once again point out that these arguments are completely rebuffed by the Federal Circuit's holding in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*":"[A]n invention need not be the best or only way to accomplish a certain result").

Furthermore, the argument that just because there are other objects having the same utility, that utility has been rendered generic and therefore invalid begs the question, previously presented, that don't all golf balls and tires have the same utility of other golf balls or tires, i.e. they can be used as golf balls or tires respectively and yet these items are readily considered to have patentable utility.

It has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; "*Langer*"); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As clearly set forth in *Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Finally, with full recognition of the fact that all patent applications are examined on their own merits and that the prosecution of one patent does not effect the prosecution of another patent, *In re Wertheim,* 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976), however the issue at hand in one

of whether the fact that patents have issued recognizing the utility of a class of molecules does this confers a statutory precedent of patentability to a broad class of compositions. Thus, there remains a lingering issue regarding due process and equitable treatment under the law. While Applicants are well aware of the new Utility Guidelines set forth by the USPTO, Applicants respectfully point out that the current rules and regulations regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claims short polynucleotides; **Exhibits M-O**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples; **Exhibit P**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), none of which contain examples of the "real-world" utilities that the Examiner appears to desire. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section IV, below), Applicants submit that the present polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Applicants agree that each application is examined on its own merits, Applicants are unaware of any

changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Appellants invention to a different standard of utility appears inconsistent and inequitable, such a judgement being arbitrary and capricious, a violation of due process and equal protection under the law and cannot be maintained.

In light of the evidence presented herewith and for the many compelling reasons described above, it is clear that the present invention clearly has utilities that are specific, substantial and credible. Therefore, Applicants submit that the rejection of the pending claims under 35 U.S.C. § 101 has been avoided and respectfully request withdrawal of the pending rejection of claims under 35 U.S.C. § 101.

IV. Rejection of Claims 1-7 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-7 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-7 have been shown by contemporaneous scientific publication to have a recognized "a specific, substantial, and credible utility", as detailed in section III above, the present rejection of claims 1-7 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1-7 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

As noted by the Action, 35 U.S.C. § 112, first paragraph, requires that the specification contain a written description of the invention. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); "*Vas-Cath*") held that an "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.*" *Vas-Cath*, at 1117, emphasis in original. However, it is important to note that the above finding uses the terms reasonable clarity to those skilled in the art. Further, the Federal Circuit in *In re Gosteli* (10 USPQ2d 1614 (Fed. Cir. 1989); "*Gosteli*") held:

> Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.

Gosteli at 1618, emphasis added. Additionally, *Utter v. Hiraga* (6 USPQ2d 1709 (Fed. Cir. 1988); "*Utter*"), held "(a) specification may, within the meaning of 35 U.S.C. § 112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses" (*Utter*, at 1714). Therefore, all Applicants must do to comply with 35 U.S.C. § 112, first paragraph, is to convey the invention with reasonable clarity to the skilled artisan.

The Action alleges that Claim 1 fails to meet the written description requirement because the claim encompasses a genus and that the specification does not provide one of skill in the art with

sufficient distinguishing characteristics. The Action then provides a summary of the PTO Guidelines (66 Fed. Reg. at 1106), the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, **or** some combination of such characteristics" (66 Fed. Reg. at 1106, emphasis added). The Federal Circuit has recently confirmed this aspect of the PTO Guidelines, wherein this exact quote was reproduced (*Enzo Biochem, Inc. v. Gen-Probe, Inc. et al.* (296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002)). Taking the exact statement from the PTO Guidelines clause by clause, the written description requirement for a claimed genus may be satisfied through disclosure of sufficiently detailed, relevant identifying characteristics, which are defined as: (a) complete or partial structure; (b) other physical and/or chemical properties; (c) functional characteristics when coupled with a known or disclosed correlation between function and structure; **or** (d) some combination of such characteristics. In other words, the written description requirement is satisfied by (a), (b), (c) **or** (d). Clause (a) states that the written description requirement may be satisfied by the disclosure of structure. The Federal Circuit has held that an adequate description of a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical properties" sufficient to distinguish the genus from other materials. *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993; "*Fiers*"). *Fiers* goes on to hold that the "application satisfies the written description requirement since it sets forth the . . . nucleotide sequence" (*Fiers* at 1607). In other words, provision of a structure and formula - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph.

Therefore, claim 1 clearly meets the written description requirement of 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

> In claims to genetic material ... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function (as seemingly required by the Action), or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the *sequence itself.*

Using the nucleic acid sequences of the present invention (as set forth in the Sequence Listing), Applicants find it hard to believe that the Examiner would allege that the skilled artisan would not readily

be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. A polynucleotide comprising 24contiguous bases of the nucleotide sequence described in SEQ ID NO: 1, could be clearly identified using SEQ ID NO:1 and the ability to count to 24.

In contrast, Applicants strongly believe that those of skill in the art would be able to choose any starting point on SEQ ID NO:1 and using the sequence listing provided differentiate between those framents (24-mers) that are encoded by SEQ ID NO:1 and those that are not.

Thus, one of skill in the art would be able to recognize whether a nucleic acid sequence comprising 24 contiguous nucleic acids of the nucleotide sequence of SEQ ID NO: 1, or a nucleotide sequence that encodes SEQ ID NO: 2, are within the genus of the instant claims, while those that lack this structural feature lie outside the genus.

Therefore it is clear that claim 1 meets the written description requirement. If one knows the full-length sequences (which are described in SEQ ID NOS: 1 of the Sequence Listing), one also knows a fragment comprising 24 or 80 contiguous nucleotides derived from said sequences. The Action cites *Fiers v. Revel*, 25 USPQ2d 1601at 1606 (CAFC 1993) and *Amgen, Inc.. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 as evidence that "the nucleic acid itself is required" (Action at page9, line 6-7). Applicants respectfully submit that the nucleic acid itself has been provided.

For each of the foregoing reasons, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has been overcome. Therefore, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph for failing to meet written description requirements be withdrawn.

VI. Rejection of Claim 1 Under 35 U.S.C. § 112, Second Paragraph

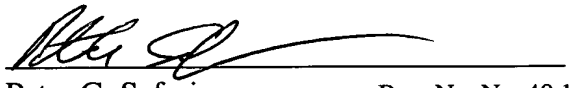
The Action rejects claim 1 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention due to the use of the word "first" in the claim. While Applicants in no way agree, in order to move the application more quickly towards allowance they have removed the offending word and thus rendered the rejection moot and therefore respectfully request the rejection be withdrawn.

VII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing amendments and remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Gamett have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

November 28, 2005
Date



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